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JUL 18 2002

# VERTEX™ Reconstruction System
## 510(k) Summary
## June 2002

**I. Company:**

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

**II. Product Name:** VERTEX™ Reconstruction System

**Classification Name:** Spinal Interlaminal Fixation Orthosis

**III. Description:**

The VERTEX™ Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS™ cable may be used with this system at the surgeon's discretion.

The VERTEX™ Reconstruction System is fabricated from medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. The VERTEX™ Reconstruction System also includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi) as described by ASTM F2063. Shape Memory Alloy is compatible with titanium or titanium alloy implants only. **Do not use with stainless steel.** Medtronic Sofamor Danek expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. **Never use stainless steel and titanium implant components in the same construct.**

To achieve best results, do not use any of the VERTEX™ Reconstruction System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic Sofamor Danek document. As with all orthopedic and neurosurgical implants, none of the VERTEX™ Reconstruction System components should ever be reused under any circumstances.

The purpose of this submission was to add 3.5mm and 4.0mm diameter bone screws along with a screw connector to the system.

## IV Indications

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the VERTEX™ Reconstruction System is indicated for the following:
DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

**Hooks and Rods**

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

**Screws/Connectors**

The use of screws (3.5mm and 4.0mm cancellous, and 4.0mm cortical) is limited to placement in T1-T3 in treating thoracic conditions only. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS™ Cable System to be used with the VERTEX™ Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

## V. Substantial Equivalence:

The VERTEX™ Reconstruction System was found to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Richard W. Treharne, Ph.D.
Senior Vice President
Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K022015
Trade/Device Name: VERTEX™ Reconstruction System
Regulatory Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: KWP
Dated: June 17, 2002
Received: June 20, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022015

Device Name: VERTEX™ Reconstruction System

Indications for Use

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the VERTEX™ Reconstruction System is indicated for the following:
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**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022015